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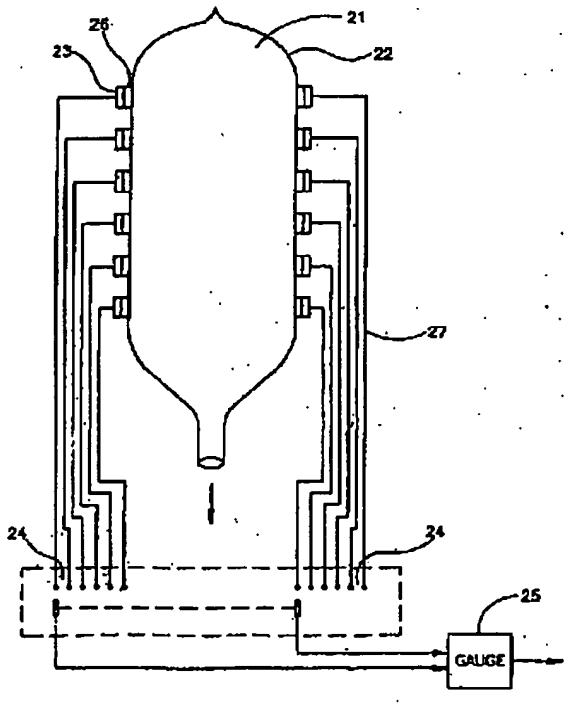
(54) Title: METHOD AND DEVICE FOR MONITORING FLUID LEVEL

(57) Abstract

A method and system for the automatic monitoring and control of patient fluid balance. The system comprises an infusion bag and urine collection bag whose volumes are monitored by means of electrodes attached to the bags. The volumes are determined by measurement of the electric capacitance and/or conductivity of the contents of the bags. A monitoring and control device connected to the bags monitors the fluid volumes and transmits control signals to a fluid pump in line with the infusion bag. In this way, the infusion and urine volumes can be monitored and the infusion volume can be automatically adapted to the patient's fluid balance.



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METHOD AND DEVICE FOR MONITORING FLUID LEVEL

FIELD OF THE INVENTION

This invention relates to a method and device for automatically monitoring and controlling intravenous delivery of fluids and monitoring body fluid excretion for improving fluid balance of patients.

BACKGROUND OF THE INVENTION

Intravenous delivery of various packed liquids, including electrolytes, chemotherapeutic drug solutions, blood products and hyperalimentation formula components is an important part of patient care. Monitoring of *"fluid balance"* is one of the most important problems in postoperative patients, because most of them cannot be fed orally, and all fluids and medications have to be administered intravenously. The amount of fluid that has to be infused is primarily dependent on the patient's needs as well as on his urine output, and therefore these parameters have to be frequently followed very carefully in the early postoperative period or during any severe illness.

Conventional automatic modular infusion pumping systems do not possess reliable technical means for automatically keeping this balance between fluid input and output. Adjustments in the prescription for the rate of delivery of intravenous fluids are periodically made by physicians and/or by observing staff, taking into consideration the fluid output of the patient. The excreted urine is usually collected through a urethral catheter into plastic bags with measure points from 100 ml to 2000 ml.

Conventional modular infusion delivery pumping systems usually do not possess an inlaid ability to automatically correct fluid input according to the urine output of the patient. This drawback is mostly due to the lack of effective fluid level sensors, controlling fluid delivery and urine output.

Conventionally, infusion fluid solutions are packed in disposable transparent plastic material bags. Similar disposable plastic material bags are also used as standard urine collectors. These collectors are an important device for care of patients suffering from inability to urinate permanently or temporarily, including disabled and geriatric patients treated in institutions or in home environment.

Usually, the appropriate measurements of the rate of fluid delivery and/or urine output are performed visually by watching and recording fluid level in the transparent disposable material bags. Such measurements are performed by the observing staff and, in some circumstances, by the patients themselves or by their caring family members. After surgery, long term monitoring of infusion and excretion volume is usually necessary. Therefore, it is very difficult to perform the concurrent manual measurements.

There are several automatic devices known in the art for liquid level detecting. For example, U.S. Pat. 5,623,252 describes a liquid level detector which utilizes audio frequency detectors for monitoring a liquid level of combustible liquids such gasoline and diesel fuel in tanks. A sensor utilizing AC and resistance measurements for determination of the liquid level of conductive liquids, and particularly conductive liquids which may contain sludge, is disclosed in U.S. Pat. 5,719,556. Further, a method and capacitance level gauge assembly for placement in a container to determine the amount or level of a substance therein is disclosed in U.S. Pat. U.S. Re. 34,601. A device for determination of a liquid level utilizing a temperature dependent foil, which is immersed in a liquid, is disclosed in U.S. Pat. 4,592,231. The total resistance of the foil is calibrated in a way to indicate a liquid level.

As far as medical applications are concerned, an automatic sensor for measurement of a body fluid excretion is described in U.S. Pat. 5,226,313.

According to this invention, the volume of the body fluid is measured using electric signals. The sensor includes a pair of electrodes placed along the volume length or height of a storage tank. Since the electric conductivity between the electrodes is a function of the volume/level of the fluid, the electric signals received from the sensor indicate the resistance value which is based upon the volume of the body fluid stored in the storage tank.

However, measurements of the dependence of the measured fluid on the electric conductivity has a serious drawback since the electric conductivity of, for example, urine may vary significantly not only among different patients, but also for the same patient during the day. Hence, the accuracy of such measurements may be insufficient, especially, when the detector is used for determination of the patient fluid balance, where the physician needs to know not only the liquid level, but also the rate of fluid delivery and/or urine output.

Therefore, precise automatic technique for measurements of the level and rate of fluid delivery and/or urine output in the field of clinical treatment would be desirable. There is also a need to facilitate and improve automatic monitoring and control of the fluid balance of individual patients.

SUMMARY OF THE INVENTION

It is therefore a general object of the present invention to provide a system for automatic monitoring and control of the fluid balance in individual patients.

It is another object of the present invention to provide new sensors for automatic measurement of the level and rate of fluid delivery and/or urine output, which may be easily and efficiently manufactured and marketed.

It is a further object of the present invention to provide new sensors for automatic measurements of the level and rate of fluid delivery and/or urine output, which is of a durable and reliable construction.

Accordingly, the system should enable the monitoring on display, e.g. at a nurses' central station, one or more of the following data:

1. Continuous measurement of the fluid amount that was already infused to the patient;
2. An alarm if the infusion has stopped for more than a few seconds.
3. Continuous measurement of urine output;
4. An alarm if the infusion bag is nearly empty;
5. An alarm when the urine bag is nearly full;
6. An automatically calculated fluid balance; and
7. Fluid balances of all the patients of the department that appear on the same display.

In accordance with the invention, the system includes a feedback central action, allowing a nurse to correct from the nursing station the rates of delivery of the fluids in the individual patients.

The sensors for automatic measurements of the level and rate of fluid delivery and/or urine output, in accordance with the invention, are integral with disposable infusion delivery bags, used for intravenous delivery of electrolyte solutions, blood and blood components, parenteral nutrition components, drug solutions, and/or urine bag collectors, etc.

The measurements of the level and rate of fluid delivery and/or urine output are achieved from electric conductivity, capacitance and/or heat emission measurements for determination of the fluid volume and rate in the infusion bags, urine collectors or any other disposable fluid containers.

In contrast to the prior art measurement techniques, the sensors, according to the present invention, instead of a pair of electrodes, utilize a plurality of electrodes attached or imprinted on the surfaces of the disposable fluid container. These technique enables to divide an analog signal coming into plurality increments, and thus, by using this discretization, to treat the signal in a digital manner.

In a first aspect the present invention provides an infusion bag having at least two pairs of electrodes attached to the external surface of substantially opposite walls of the bag and being capable of measuring electric capacitance

indicative of the fluid volume in the bag.

In a second aspect the present invention provides a container for collecting excreted body fluids having at least two pairs of electrodes attached to the external surface of substantially opposite walls of the container and being capable of measuring electric capacitance indicative of the fluid volume in the container.

In a third aspect the invention provides a container for collecting excreted body fluids having a plurality of electrodes attached to the inner surface of the container and being capable of measuring electric conductivity indicative of the fluid volume in the container, wherein the electrodes comprise a series of electrodes whose distal ends are at progressively increasing distances from the distal end of the container.

In a fourth aspect of the invention, there is provided a system for automatic monitoring and control of the fluid balance of the individual patients fluid balance at clinical departments comprising:

(a) an infusion bag according to the invention capable of being connected to said patient;

(b) a fluid pump connected to said infusion bag;

(c) a urine collecting container according to the invention capable of being connected to said patient; and

(d) a monitoring and control device connected to (a), (b) and (c) for receiving data from (a) and (c) and sending control signals to (b).

In a fifth aspect of the invention, there is provided a method of automatic monitoring and control of the fluid balance of the individual patients fluid balance at clinical departments comprising the following steps:

(a) connecting an infusion bag according to the invention to a patient through a fluid pump;

(b) connecting a urine collecting container according to the invention to said patient;

(c) connecting a monitoring and control device to said infusion bag, urine collecting container and fluid pump;

(d) monitoring the fluid volume in said infusion bag and urine collecting container by said device; and

(e) calculating the fluid balance of said patient and changing it if necessary by controlling the flow rate of said fluid pump.

The term *plurality* in this specification refers to more than two.

BRIEF DESCRIPTION OF THE DRAWING

In order to understand the invention, its operating advantages and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic illustration of one embodiment of a monitoring system based on electric capacitance measurements;

Fig. 2 is a typical curve of capacitance as a function of volume;

Fig. 3 is a schematic illustration of another embodiment of a container according to the invention;

Fig. 4 is a schematic illustration of a further embodiment of a container according to the invention with a temperature-dependent sensor;

Fig. 5 is a block diagram illustrating one embodiment of the system of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference will now be made in detail to the description of the invention in conjunction with the preferred embodiments thereof. It should be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawing. The invention is intended to cover alternatives, modifications and equivalents and capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description

and should not be regarded as limiting.

Referring now to Fig. 1, there is shown a schematic illustration of one embodiment of a container, such as an infusion bag or an urine collector, according to another embodiment of the invention, according to the invention.

According to this embodiment, a container 21 having flexible walls 22 made of a substantially nonconductive material integrated with a plurality of substantially conductive strips 23 attached to the outer surface of the walls along the longitudinal axis of the container. The electrodes are coupled via wires 27 through a multiplexing switcher 24 to a gauge 25 capable of capacitance measurements.

The electrodes should be of sufficient size in order to provide a possibility to measure an electric capacitance of a capacitor formed by any pair of the electrodes. This capacitance will be proportional to the electrode area and the dielectric permittivity of the liquid filling the container, and it is inversely proportional to the distance between the electrodes. Preferably, for increasing the value of the capacitance formed by any pair of the electrodes, and correspondingly the accuracy of the measured volume, a layer 26 of material having a high dielectric permittivity should be placed between the walls 22 and the electrodes 23. This layer, for example, may be made of therylene.

During operation, the shape of the container changes resulting in a change in the distance between the electrodes, and correspondingly in the measured capacitance. Fig. 2 shows a typical curve of the dependence of the capacitance C between any pair of electrodes upon the volume of the container in the case when the container is filling up. After a corresponding calibration, these capacitance changes may be related to the corresponding changes of the liquid volume filling the container and may be monitored on the gauge 25 graduated in the volume units.

Referring now to Fig. 3, there is shown a schematic illustration of a monitoring device utilizing a medical container, such as an urine collector, according to another embodiment of the invention.

This container includes two communicating compartments. A compartment 1 servers for receiving the excreted body urine 3 via a catheter 4 coupled to the patient's bladder (not shown). A compartment 2 includes a sensor 5 utilizing electric conductivity measurements of the urine. The utilization of two compartments instead of just one is preferable in order to prevent measurement errors due to the irregular influx of the urine.

The sensor includes a plurality of electrodes, one of which is formed as a continuous general vertical line electrode 6. The other electrodes 7 extend along the height of the measured volume. These electrodes at one end have a contact point sites 8, and are arranged with progressively increasing distances from the distal end of the container. Since urine is an electro-conductive fluid, electrical shorting between one of these point sites and a continuous line electrode 10 allows determination of the urine level. All the electrodes at the second end are connected by outlets with a general connector 9, connecting the sensor with a gauge device (not shown) monitoring the liquid volume.

In contrast to the prior art techniques which utilize a pair of electrodes for monitoring the liquid level by electric conductivity measurements, utilizing a plurality of electrodes enables to divide an analog signal into a plurality of increments, and thus, by using this discretization, to treat the signal in a digital manner.

In order to provide a value for the liquid volume between two separated point sites, a correction procedure can be used. According to the procedure, the volume magnitude between the magnitudes V_i and V_{i+1} may be approximately determined from the equation:

$$V = V_i + V_1 \frac{R_i - R_{i-1}}{R_{oi} - R_{i-1}} ,$$

where R_i is the magnitude of the electrical resistance (or conductivity) between the general electrode 6 and the electrode having a number i; and R_{oi} is the magnitude of the electrical resistance (or conductivity) between the electrides having numbers i and $i-1$.

Referring now to Fig. 4, there is shown a schematic illustration of a monitoring device utilizing a medical container according to still another embodiment of the invention. According to this embodiment, a collector 41, that may be, for example, a conventional urine collector, connected through a tube 42 to the urine catheter 43. For automatic monitoring of the patient's urine output a pair of flexible average temperature sensors 44 and 45 are inserted in the container and are arranged along the longitudinal axis of the container. The function of one of these average temperature sensors is heat emission and a function of the second average temperature sensor is to measure an effective temperature of the air and urine inside the urine collector. These flexible sensors via a wire 46 are connected to a signal gauge device (not shown) for continuous quantitative monitoring of the urine volume in the urine bag collector.

In operation, when urine in the bag collector is absent, the main average temperature sensor has a predetermined value of the electrical resistance R. The coefficient of the heat transmission changes after urine has entered the bag collector. Therefore, the temperature of the sensor increases together with the increase of its resistance upto the value R_1. Therefore, the quantity of the urine in the bag collector is a function of the value R_1- R.

A second temperature sensor, which measures an effective temperature of the air and the urine according to the quantity of the urine inside the collector, is defined as a compensatory sensor. Flexible average temperature sensors may express a measure of non-linearity according to variability of the shapes of the urine bag collectors.

A special gauge device for continuous/interval urine output indication and registration is connected to a special analog or a digital display with an alarm (not shown). An algorithm in the said indication/registration gauge device takes into consideration an integral and differential values of the quantitative dynamics of the urine output. The data, including net urine output, hourly and minute urine output appear constantly on the said analog/digital display and then alarm signals to observing/caring staff and/or to the patients themselves.

Measurement of capacitance values may provide the possibility of determining the following parameters:

1. Continuous measurement of the amount of the fluid that was already infused into the patient.
2. To set an alarm if the infusion has stopped for more than a few seconds.
3. To set an alarm when the infusion bag is nearly empty.
4. To provide continuous measurement of urine output.
5. To set an alarm when the urine bag is nearly full to its capacity.
6. A fluid balance may be calculated automatically in the morning or whenever desired during the day or night.
7. All the patients' fluid balances of the department will appear on the same display (screen) at the central nursing station.

In order to clarify the principles of the method and the components of the system described above, reference is made to Fig. 5 in which:

P_1 patient 1

P_2 patient 2

IBI infusion disposable bag with inlaid sensor (fluid delivered from bag by gravitation)

IB2 infusion disposable bag with inlaid sensor (fluid delivered from bag with the help of automatic pumping provided by APS).

APS automatic pumping system (e.g. Ivac).

S_{-1} a sensor inlaid in a disposable infusion bag.

UB disposable urine bag collector.

S_2 sensor inlaid in a disposable urine bag collector.

S-6 signal gauge device, coupled with radio or infrared or other means transmitter and also providing warning in the immediate vicinity.

RC radio or infrared or other means further signal transmission channel.

M_1 modem 1 (intermediate transmission station 1).

M_2 final transmission station.

VLD logic device (may be PC) in the central nurse station.

D display in a central nurse station

TM illustrating possibility of the immediate delivery of information through telephone modem

>< feeding of information from sensors to PC and feedback correction from PC to periphery.

As such, those skilled in the art to which the present invention pertains can appreciate that while the present invention has been described in terms of a preferred embodiment, the conception, upon which this disclosure is based, may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present invention.

It is important, therefore, that the scope of the invention is not to be construed as limited by the illustrative embodiments set forth herein, but is to be determined in accordance with the appended claims.

CLAIMS:

1. An infusion bag having at least two pairs of electrodes attached to the external surface of substantially opposite walls of the bag and being capable of measuring electric capacitance indicative of the fluid volume in the bag.

2. An infusion bag according to Claim 1 which is disposable.

3. An infusion bag according to Claim 1 wherein said electrodes are integral with the walls of the bag.

4. An infusion bag according to Claim 1 wherein said electrodes are printed on the walls of the bag.

5. A container for collecting excreted body fluids having at least two pairs of electrodes attached to the external surface of substantially opposite walls of the container and being capable of measuring electric capacitance indicative of the fluid volume in the container.

6. A container according to Claim 5 wherein said body fluid is urine.

7. A container according to Claim 5 which is disposable.

8. A container according to Claim 5 wherein said electrodes are integral with the walls of the container.

9. A container according to Claim 5 wherein said electrodes are printed on the walls of the container.

10. A container for collecting excreted body fluids having a plurality of electrodes attached to the inner surface of the container and being capable of measuring electric conductivity indicative of the fluid volume in the container, wherein the electrodes comprise a series of electrodes whose distal ends are at progressively increasing distances from the distal end of the container.

11. A container according to Claim 10 which is disposable.

12. A container according to Claim 10 wherein said container has two separate compartments, a first compartment for receiving the excreted body fluid and a second compartment containing the electrodes, wherein said second compartment is in fluid communication with said first compartment.

13. A container for collecting excreted body fluids comprising a heat emission sensor capable of indicating the fluid volume in the container.

14. A system for the automatic monitoring and control of patient fluid balance comprising:

(a) an infusion bag according to Claim 1 capable of being connected to said patient;

(b) a fluid pump connected to said infusion bag;

(c) a urine collecting container according to any of Claims 5, 10 or 13 capable of being connected to said patient; and

(d) a monitoring and control device connected to (a), (b) and (c) for receiving data from (a) and (c) and sending control signals to (b).

15. A system for the automatic monitoring of patient fluid balance comprising:

(a) an infusion bag according to Claim 1 capable of being connected to said patient;

(b) a urine collecting container according to any of Claims 5, 10 or 13 capable of being connected to said patient; and

(c) a monitoring device connected to (a) and (b) for receiving and displaying data from them.

16. A method for automatically monitoring and controlling patient fluid balance comprising the following steps:

(a) connecting an infusion bag according to Claim 1 to a patient through a fluid pump;

(b) connecting a urine collecting container according to any of Claims 5, 10 or 13 to said patient;

(c) connecting a monitoring and control device to said infusion bag, urine collecting container and fluid pump;

(d) monitoring the fluid volume in said infusion bag and urine collecting container by said device; and

(e) calculating the fluid balance of said patient and changing it if necessary by controlling the flow rate of said fluid pump.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 99/00695

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/168 A61B5/20 G01F23/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 3 919 455 A (SIGDELL JAN-ERIK ET AL) 11 November 1975 (1975-11-11) column 3, line 48 -column 4, line 52; figures 3,4	5-8, 10-12 1-4
Y	US 5 135 485 A (COHEN LOUIS ET AL) 4 August 1992 (1992-08-04)	1-4
A	column 2, line 17 -column 3, line 26 column 7, line 39 -column 8, line 10; figure 6	5-9
A	FR 2 752 297 A (POIRIER MARC) 13 February 1998 (1998-02-13) page 4, line 28 -page 5, line 15; figures	1-9

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 4 291 692 A (BOWMAN ROBERT J ET AL) 29 September 1981 (1981-09-29) column 3, line 15 -column 5, line 58 column 7, line 3 - line 68; claims; figures	14,15
A	US 5 226 313 A (MURATA MICHIHIRO ET AL) 13 July 1993 (1993-07-13) cited in the application the whole document	5-9
X	GB 2 243 918 A (MURATA MANUFACTURING CO) 13 November 1991 (1991-11-13) page 5, line 1 -page 7, line 3	10-12
A	page 1, line 1 -page 2, line 14 page 11, line 3 - line 16; claims; figures	1-9,13
X	WO 95 05774 A (URITEL BV ;WIJKSTRA HESSEL (NL); KERSTEN PETRUS LEONARDUS (NL)) 2 March 1995 (1995-03-02) page 4, line 13 -page 7, line 11; figures	10,11
A	DE 26 23 557 A (POERTENER JUERGEN DR MED) 8 December 1977 (1977-12-08) page 6, line 6 -page 8, line 15; figures	10-12

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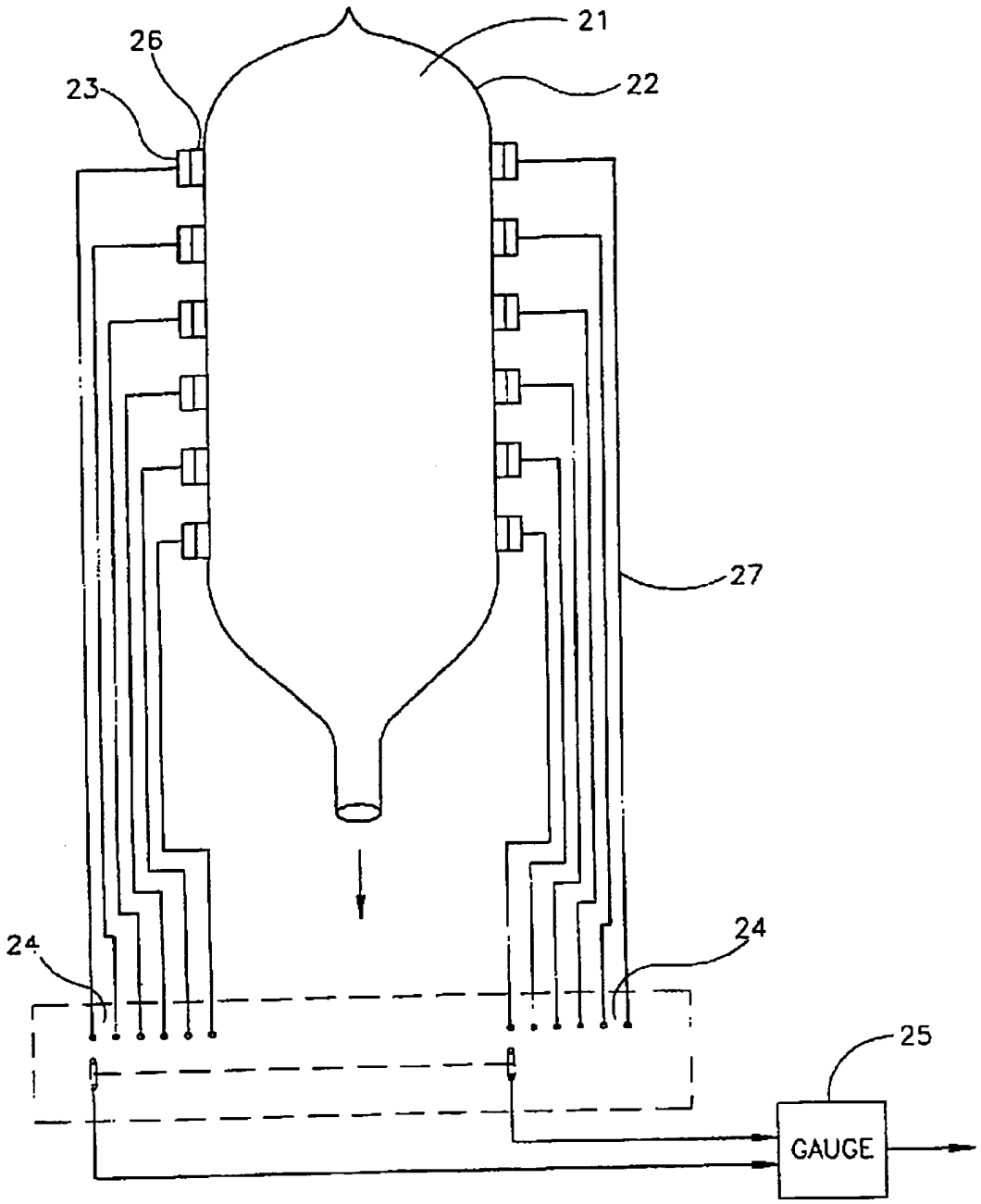

FIG.1

FIG.2

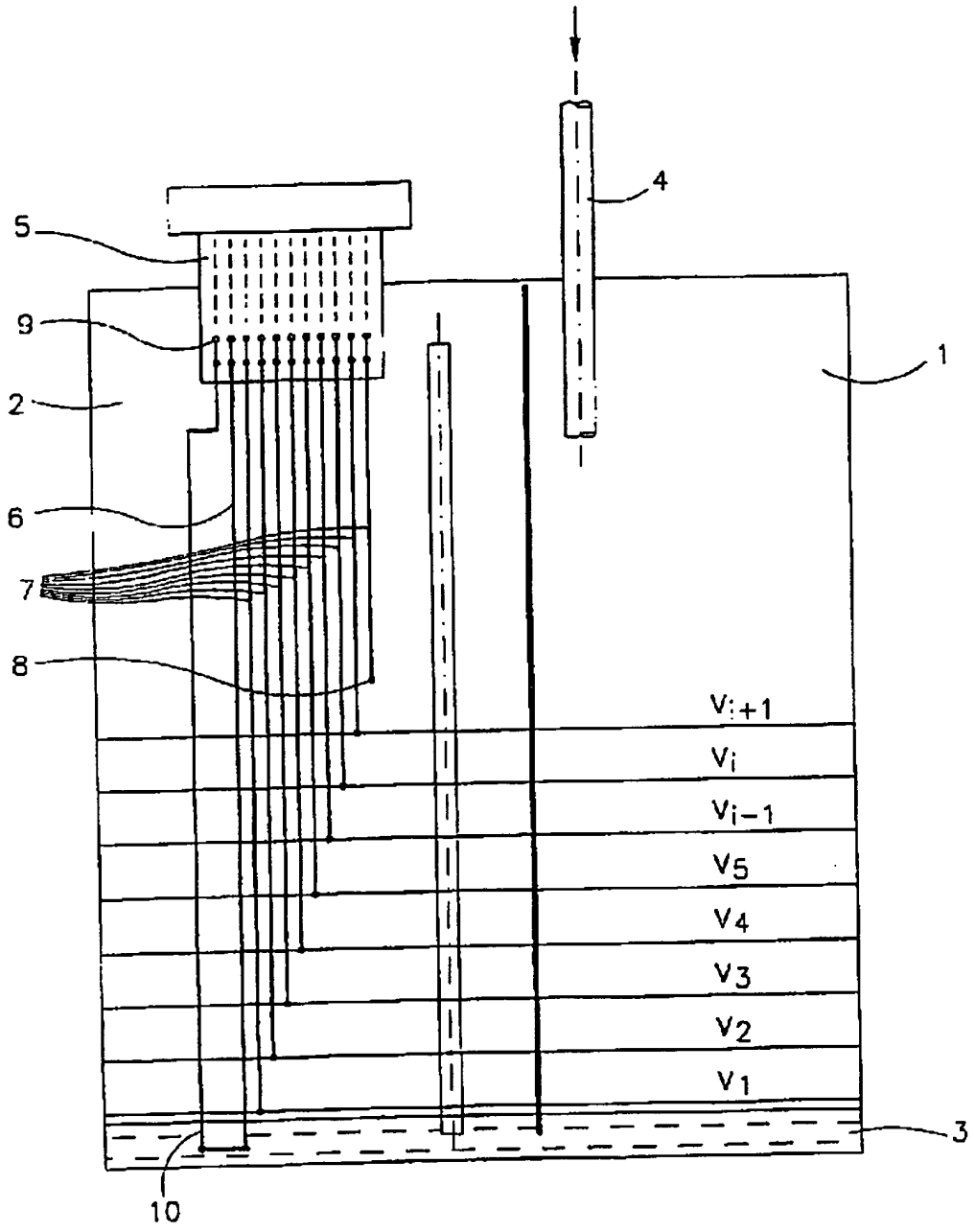

FIG.3

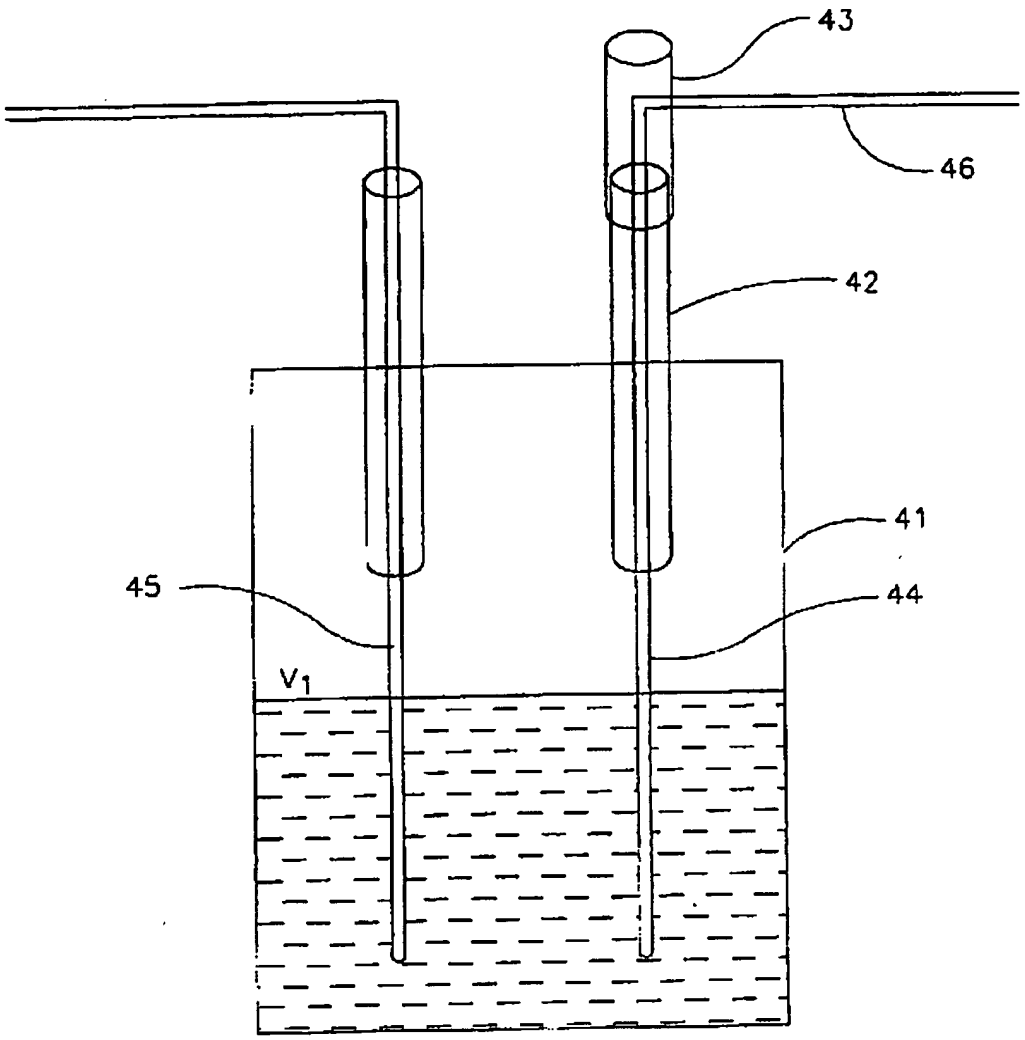

FIG.4

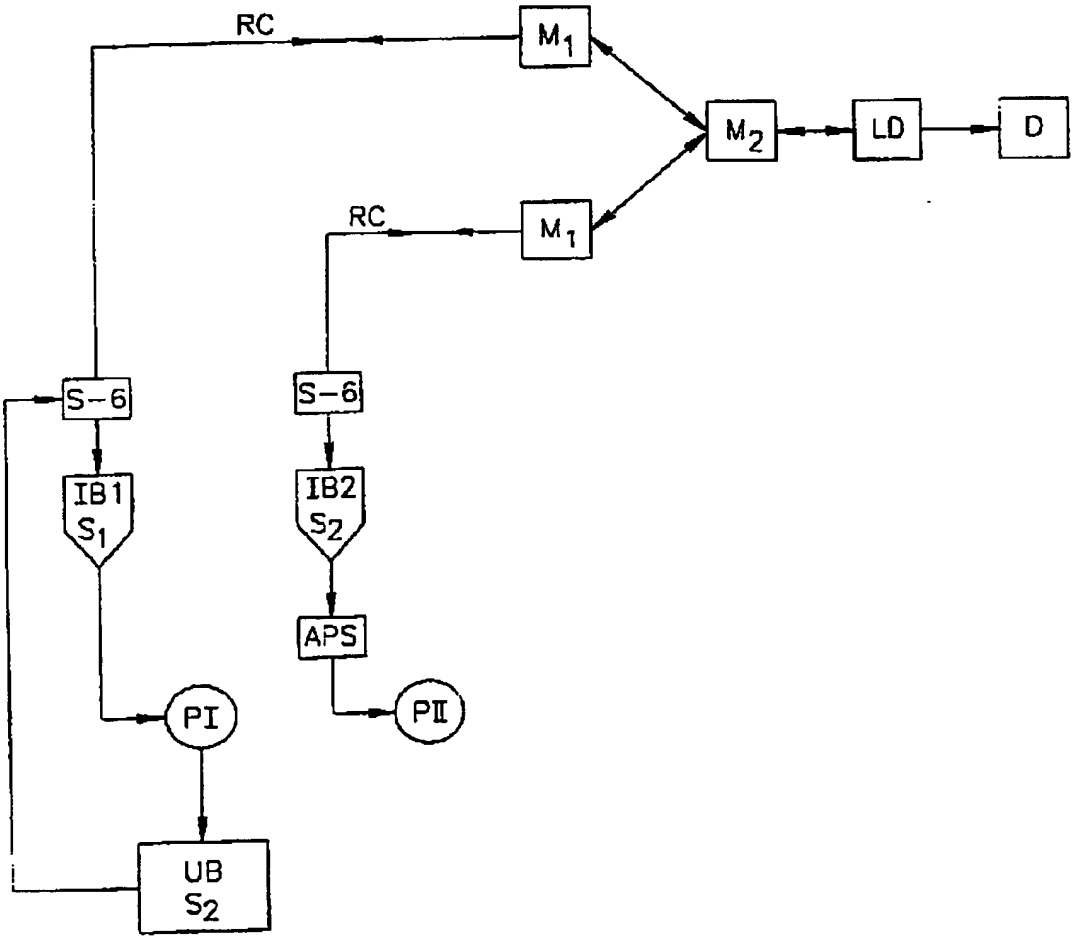

FIG.5